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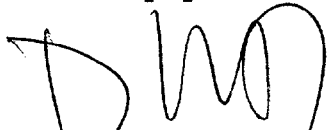
RE: Document #97N-484S

Dear Sirs:

I am an orthopedic surgeon who frequently uses bone allografts in the operating room. The bone banks from which we obtain the allografts are already carefully supervised and regulated. The allograft materials are always carefully handled by the hospital, and we, as orthopedic surgeons, use them as needed for the benefit of our patient's. I see no need to regulate allografts as a medical device. I believe that trying to institute such regulation would be detrimental to patient care, and that it would curtail our use of bone allografts and make the process of obtaining and using them so extensive as to limit their availability. Then we would not be able to obtain the allografts, which we need for patient care, or they might become prohibitively expensive.

I appreciate your attention to this and please feel free to contact me as needed.

Sincerely yours,



David J. Schulak, M. D.
DJS/pb

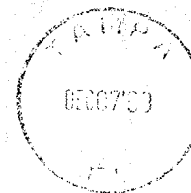
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